Electronic Mail Message

Date: 1/4/00 9:59:50 PM
From: owner-e-drug (owner-e-drug@usa.healthnet.org)
Subject: [e-drug] To: E-drug <e-drug@usa.healthnet.org>

To: e-drug@usa.healthnet.org
From: Peter Lurie <PLURIE@citizen.org>
Subject: ICH guidelines on control groups in clinical trials

E-drug: ICH guidelines on control groups in clinical trials

E-druggers:

Recently we submitted comments to the U.S. Food and Drug Administration on an International Conference on Harmonisation (ICH) document on the choice of control groups in clinical trials. The document is in significant part an attack on active-controll http://www.citizen.org/hrg/PUBLICATIONS/1503.htm

We urge those of you in Japan and Europe (the other participants in ICH), in particular, to bring these comments to the attention of the appropriate drug regulatory authories in your countries.

Below are excerpts from our letter.

Peter Lurie, MD, MPH
Deputy Director
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, DC 20009
Phone: (202)588-7781
Fax: (202)588-7796
Email: plurie@citizen.org
Web address: http://www.citizen.org

To whom it may concern:

The Draft Guidance on Choice of Control Group in Clinical Trials, prepared as part of the International Conference on Harmonisation (ICH), is a clear attempt by the Food and Drug Administration (FDA) to spread its pro-placebo-controlled trial ideology participated in April of this year. Dr. Robert Temple, Director of the FDA's Office of Medical Policy, stated at the meeting, "And people do active control trials in Europe all the time. Europe is finally getting the idea that they need to add a placeb employee(2),(3),(4),(5) and would take on added force if this poorly thought-out Guidance were finalized and adopted by other ICH countries.

99D-3082

C 5

The zeal to expand the use of placebos in clinical trials has resulted in a document that is so unbalanced that its credibility is undermined. The structure of the document reflects that bias:

- An entire section (section 1.5) is devoted to attacking active-controlled trials; there is nothing similar for any of the other study designs, even clearly weaker designs such as historical controls.
- This section attacking active-controlled trials actually precedes the detailed descriptions of the types of controls, so the reader is poisoned against active-controlled trials before he or she even learns fully about them.
- The purported weaknesses of active-controlled trials are mentioned repeatedly, leading to an extremely redundant and tedious document.
- Ethical considerations are treated as subordinate to supposed data collection needs; ethics does not even appear in the critical Table 1, which describes the attributes of the different trial designs. The question onfronting researchers is not an provide the most useful data while maximizing the protection of patients?" When ethical concerns are quite literally out of the picture, researchers will be led to the first question instead. The Draft Guidance is a transparent attempt to legitimi

In addition to its attempts to water down the existing ethical codes, the document places undue emphasis on the supposed needs of regulators and pharmaceutical companies (who together make up the ICH) and places these above the needs of patients or phy existing drug. But the proposed Guidance would drive clinical trials in the opposite direction. While this may make things easier for regulatory bodies, which can approve drugs simply on the basis of superiority to placebo, and to the pharmaceutical in

[snip]

In summary, this Draft Guidance is a remarkably biased description of the advantages and disadvantages of various clinical trial designs. The document continues the FDA's longstanding assault on active-controlled trials and does so at a time where there is less clinical and ethical justification for such trials than ever. Rather than challenging investigators to obtain the best possible data using an ethical design, the Draft Guidance subordinates these ethical concerns to the reflexive tendency of some researchers to prefer placebo-controlled studies, to the short-sighted interpretations of drug regulatory authorities bent on approving any drug as long as it is somewhat better than nothing, and to the concerns of the pharmaceutical industry.

Yours sincerely,

Peter Lurie, MD, MPH
Deputy Director
Public Citizen's Health Research Group

Curt Furberg, MD, PhD
Professor
Wake Forest University School of Medicine

Sidney M. Wolfe, MD
Director
Public Citizen's Health Research Group

Send mail for the `E-Drug' conference to `e-drug@usa.healthnet.org'.
Mail administrative requests to `majordomo@usa.healthnet.org'.
For additional assistance, send mail to: `owner-e-drug@usa.healthnet.org'.